UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): January 4, 2018

GALECTIN THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-31791**	**04-3562325**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4960 PEACHTREE INDUSTRIAL BOULEVARD, Ste 240
NORCROSS, GA 30071
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (678) 620-3186

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On January 4, 2018, Galectin Therapeutics Inc. (the "Company) posted to its website a corporate presentation focusing on the results of its NASH-CX clinical trial attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Galectin Therapeutics Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Galectin Therapeutics Inc.

Date: January 4, 2018

By: /s/ Jack W. Callicutt
Jack W. Callicutt
Chief Financial Officer

Exhibit 99.1

Galectin Therapeutics

GR-MD-02 for Indication of NASH Cirrhosis

NASH-CX Clinical Trial Results

San Francisco, CA

January 8-11, 2018

NASDAQ: GALT

www.galectintherapeutics.com

Forward Looking Statements

This presentation contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future performance and use words such as “may,” “estimate,” “could,” “expect” and others. They are based on our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements.

These statements include those regarding the potential therapeutic benefits of our drugs and specifically the results of our NASH-CX clinical trial. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others that:

- the data presented today represent a top line analysis, and there may be changes in the final clinical trial report due to further analysis of the full data set including additional statistical analysis;
- subsequent trials, if any, in whatever patient population chosen may fail to validate any positive results of our trial now concluded;
- future phases or future clinical studies could prove prohibitively time consuming and/or costly;
- plans regarding development, approval and marketing of any of our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies;
- strategies, personnel, and spending projections may change;
- due to the novel nature of our compounds, future phases of manufacturing scale-up and supporting chemical and physical characterizations for both trials and commercial purposes can be challenging and costly and there is no certainty this can be accomplished nor certainty it would acceptable to regulators;
- we may be unsuccessful in developing partnerships or other business relationships with other companies or obtaining capital that would allow us to further develop and/or fund any future studies or trials or sell or license our intellectual property; and, further,
- there is the uncertainty that any drug in development could obtain regulatory approval in any patient population.

To date, we have incurred operating losses since our inception, and our future success may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2016, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

Galectin is a Development Phase Biotech Company with an Experienced Team

Peter G. Traber, M.D., President, CEO, CMO

- Recognized leader in gastroenterology and hepatology
- University of Pennsylvania Chief of Gastroenterology; Chairman of Internal Medicine; CEO of Health System, Dean of Medicine
- Baylor College of Medicine, President and CEO
- GlaxoSmithKline, Senior Vice President and Chief Medical Officer

Harold H. Shlevin, Ph.D., COO & Corporate Secretary

- Over 34 years of relevant experience
- Solvay Pharmaceuticals, CEO
- CIBA Vision Ophthalmics (n/k/a Novartis Vision), SVP & co-founder
- Tikvah Therapeutics, Founder and CEO
- CIBA-Geigy Pharmaceuticals

Jack W. Callicut, CFO

- Over 27 years of relevant experience
- Reach Health, CFO,
- Vystar Corporation, CFO,
- Corautus Genetics, Deloitte

Eli Zomer, PhD, Pharm Development

- Over 34 years of relevant experience: Koor Biotechnologies, Charm Sciences, Glycogenesis, HU Medical School (Jerusalem), and Harvard University

Adam Allgood, Pharm D., Clinical Development

- Over 28 years experience in regulatory affairs, clinical development and medical affairs
- UCB Inc., Abbott Laboratories, Solvay Pharmaceuticals

Rex Horton, Regulatory

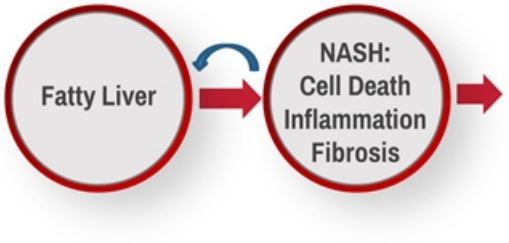
- Over 26 years of experience; Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics; Georgia Institute of Technology

Developing Treatments Where Galectin-3 Protein is Implicated in Disease

Clinical Phase Studies With Galectin-3 Inhibitor GR-MD-02

- **Primary Program is in NASH Cirrhosis (topic of this presentation)**
- **Combination Cancer Immunotherapy**
  - Investigator initiated phase 1b clinical trial of GR-MD-02 in combination with KEYTRUDA in advanced melanoma and other malignancies
  - Encouraging early data with 5 of 8 responders (2 CR and 3 PR) in advanced melanoma
- **Psoriasis and Atopic Dermatitis**
  - Small open label studies show clinically significant effect, demonstrating activity of drug in human disease

Targeting NASH Cirrhosis



Progression to Cirrhosis (5%)

Cirrhosis Stage[1]	*Stage 1*	*Stage 2*	*Stages 3 and 4*
Clinical	*Compensated* *No varices or complications*	*Compensated* *Varices present*	*Decompensated* *Complications*
Hemodynamic (HVPG, mmHg)	> 6	> 10	> 12
Biological	*Scar and X-linking*	*Thick (acellular) scar and Nodules*	*Insoluble scar*

Estimated US Prevalence

80-100M	**24-30M**	**3-5M**	**1.5-2.5M**	**1.5-2.5M**

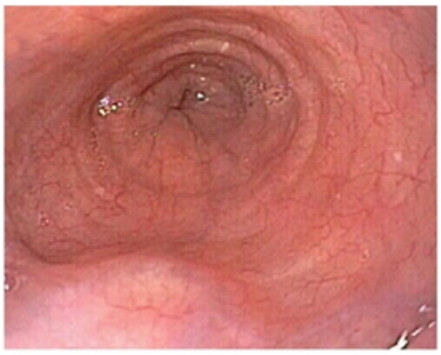
NASH-CX Trial Showed Positive Efficacy in Compensated NASH Cirrhosis Without Varices

[1] *Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:14451449*

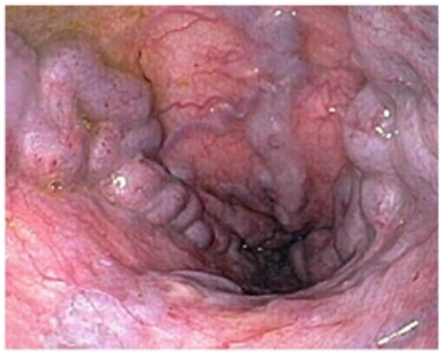
Critical Importance of Esophageal Varices in NASH Cirrhosis

An important goal of treatment of patients with Stage 1, compensated cirrhosis without esophageal varices is to prevent progression to varices and complications

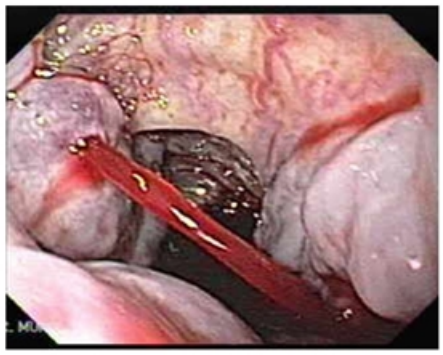
Esophagus: No Varices



Esophageal Varices



Bleeding Esophageal Varices



NASH Cirrhosis Development Program: Summary

- Gal-3 null mice are resistant to development of NASH [1] and liver fibrosis [1, 2]
- GR-MD-02 is a glycopolymer (polysaccharide), considered a Nonbiological Complex Drug (NBCD) that binds to galectin-3 protein, has strong patent protection, and is administered intravenously
- GR-MD-02 has robust efficacy in pre-clinical models of NASH and toxic cirrhosis, with action at a nexus of multiple pathophysiological processes [3, 4]
- Well tolerated and safe in preclinical toxicology and clinical trials (2 P1, P2a and P2b)
- *NASH-CX phase 2b clinical trial showed clinically meaningful positive results of GR-MD-02 in patients with NASH cirrhosis without esophageal varices (Stage 1 Cirrhosis)*
- NASH-CX trial identified endpoints and patient population that can form the basis of phase 3 trials in NASH cirrhosis without esophageal varices

[1] Journal of Hepatology 2011;54:975-983

[2] PNAS 2006;103:5060-5065

[3] Traber PG and Zomer E.PLOS ONE 2013;8:e83481

[4] Traber PG, Chou H, Zomer E, Hong F, Klyosov A Fiel M-I, Friedman, SL. PLOS ONE 2013;8:e75361.

NASH-CX Clinical Trial Design[1]

Major Inclusion Criteria

NASH cirrhosis (biopsy)
HVPG ≥ 6 mmHg
No cirrhosis complications
No or small varices

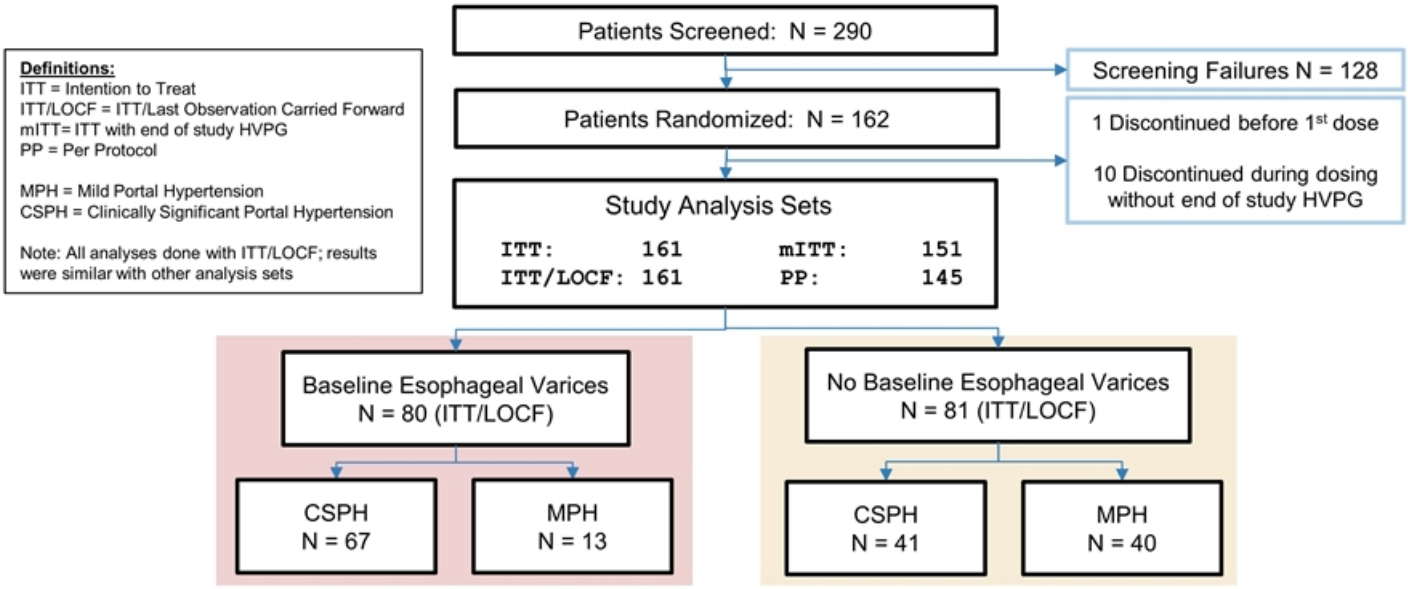
Every other week infusion X 26

Placebo (54)
GR-MD-02 2 mg/kg (54)
GR-MD-02 8 mg/kg (54)

		Baseline	*Week 26*	*Week 54*
Primary endpoint	HVPG[2]	X		X
Secondary endpoints	Liver Biopsy[3]	X		X
	FibroScan	X	X	X
	MBT[4]	X	X	X
	Complications[5]	X		X
	Endoscopy	X		X

[1] All subjects were enrolled across 36 sites in the US (Appendix 1)
[2] HVPG = Hepatic Venous Pressure Gradient
[3] Histologic staging & quantitative morphometry for collagen
[4] MBT = ^{13}C Methacetin Breath Test
[5] Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)

Patient Populations

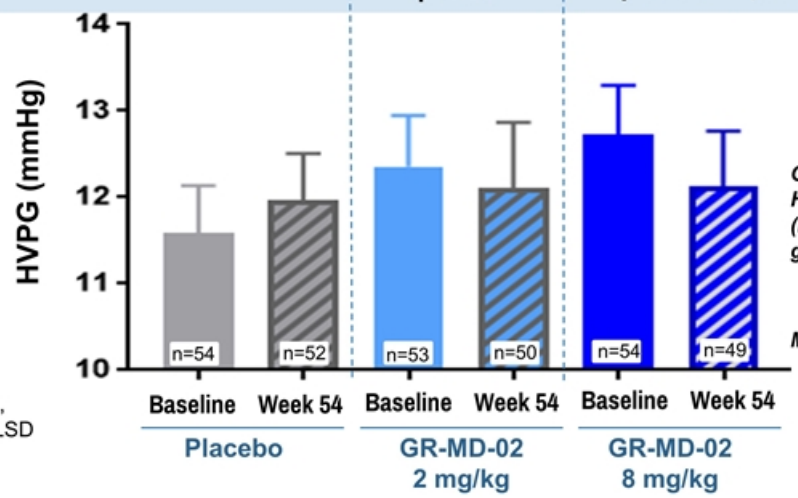


Demographic characteristics (age, gender, BMI, nationality, diabetes) and baseline HVPG measurements were balanced across the three treatment groups in study analysis sets (Appendices 2 & 3)

HVPG Primary Endpoint: Total Patient Population

1. Trend toward benefit with drug, but not statistically significant
2. Drug effect was significantly dependent on dose*varices in total group (p<0.02)

Mean Change From Baseline to Week 54[1]	0.3	-0.37 p=0.45 p=0.14	-0.42 p=0.49 p=0.09	(Absolute Change) (Percent Change)



Overall mean baseline HVPG=12.22 mmHg (No significant difference between groups at baseline-ANOVA)

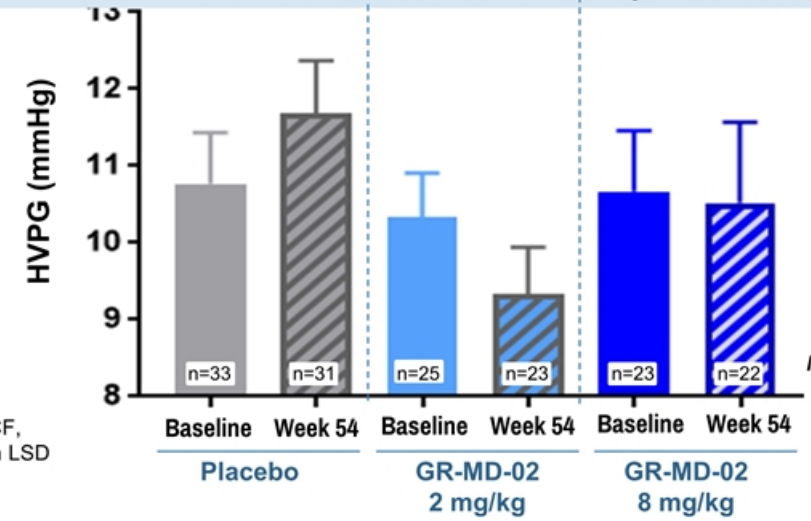
Mean ± SEM

[1]ITT with LOCF, ANCOVA with LSD

NASH Cirrhosis Without Varices at Baseline (50% of total population)

Statistically significant effect of 2 mg/kg dose on absolute change in HVPG

Mean Change From Baseline to Week 54[1]	0.8	-1.08	0.15	
		p < 0.01	p = 0.36	(Absolute Change)
		p = 0.01	p = 0.17	(Percent Change)



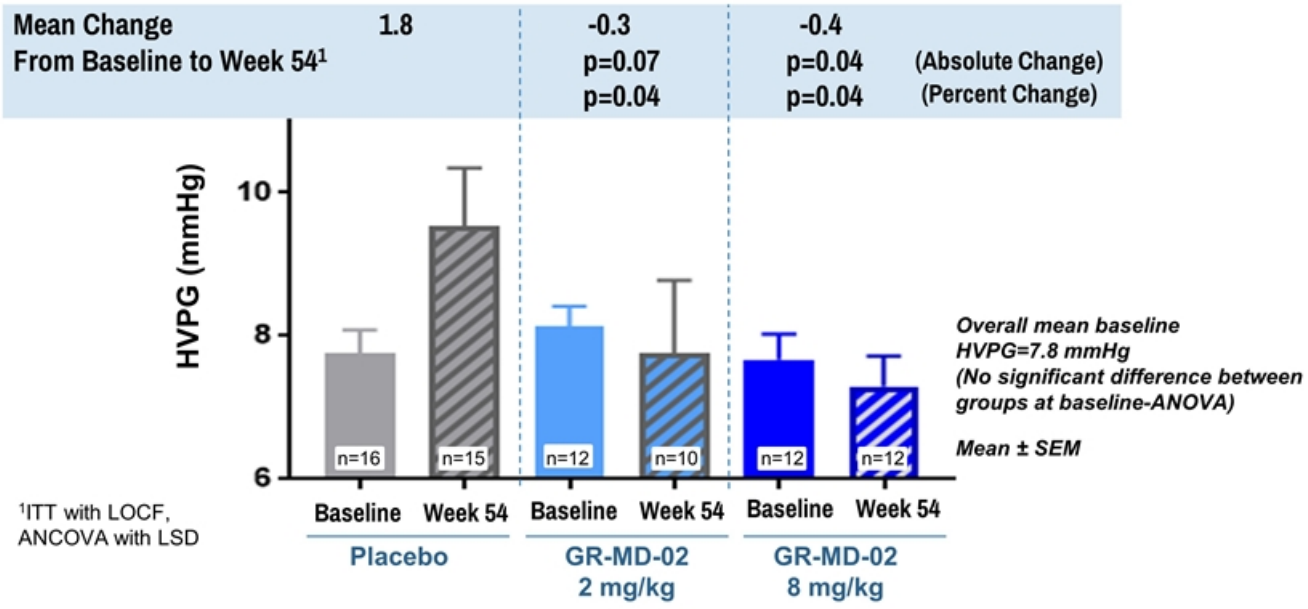
Overall mean baseline HVPG=10.6 mmHg (No significant difference between groups at baseline-ANOVA)

Mean ± SEM

[1]ITT with LOCF, ANCOVA with LSD

No Varices at Baseline: Mild Portal Hypertension (≥ 6 and <10 mmHg)

Statistically significant effect of both doses on change in HVPG in mild portal hypertension

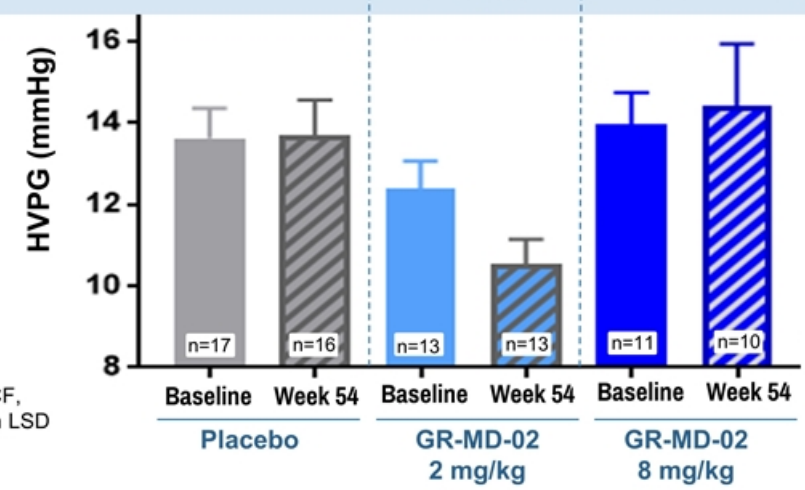


[1]ITT with LOCF, ANCOVA with LSD

No Varices at Baseline: Clinically Significant Portal Hypertension

Statistically significant effect of 2 mg/kg dose on change in HVPG

Mean Change From Baseline to Week 54[1]	**-0.1**	**-1.8**	**0.7**	
		P = 0.06	**ns**	**(HVPG ≥ 10)**
		P = 0.02	**ns**	**(HVPG > 10)**



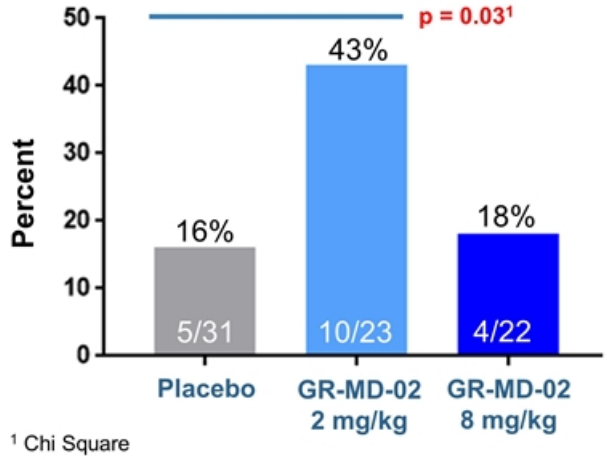
Overall mean baseline HVPG=13.4 mmHg (No significant difference between groups at baseline-ANCOVA)

Mean ± SEM

[1]ITT with LOCF, ANCOVA with LSD

Responder Analysis in Patients Without Varices at Baseline

Percentage of Patients Who Had a Clinically Relevant Reduction in HVPG With ≥ 2 mmHg Decrease From Baseline

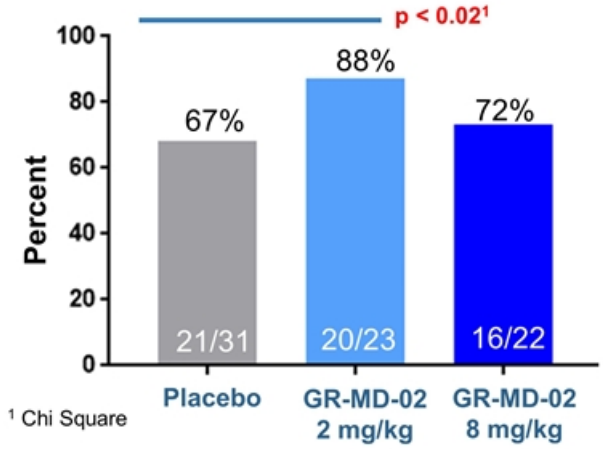


[1] Chi Square

Rigorous definition of efficacy because it requires a clinically important *reduction* in HVPG from baseline

Responder Analysis in Patients Without Varices at Baseline

Percentage of Patients Who Had a Clinically Relevant Reduction in HVPG with ≥ 2 mmHg Decrease From Baseline PLUS No Change From Baseline Defined as < ± 2 mmHg



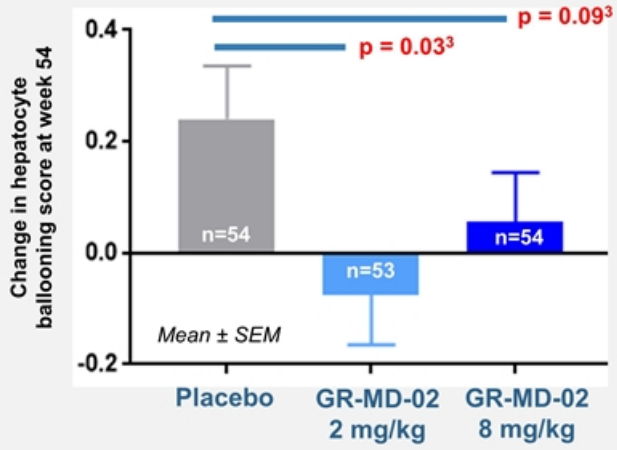
[1] Chi Square

Statistically Significant Improvement of Hepatocyte Ballooning on Liver Biopsy

- There was a statistically significant improvement in hepatocyte ballooning (liver cell death) with GR-MD-02 (2 mg/kg) and a strong trend with 8 mg/kg compared to placebo
- The reduction in ballooning hepatocytes with GR-MD-02 correlates with what was seen in NASH animal models[1]
- NAFLD activity score had a trend towards improvement because of improved ballooning, but not statistically significant
- No differences in steatosis or inflammation scores
- No differences in fibrosis staging or % collagen on morphometry, but not powered for these endpoints

[1] *Traber PG and Zomer E. PLOS ONE 2013;8:e83481*

Total Study Patient Population[2]



[2] ITT with LOCF (161) [3] Ordinal Logistic Regression Analysis

Cirrhosis Complications[1]

In patients without varices, there were statistically significant fewer new varices that developed in treatment groups versus placebo

	Patients with at least one complication			
	PLB	**GR2**	**GR8**	***Comments***
Intention to Treat Group (n=161)	**11 (54)**	**8 (53)**	**7 (54)**	No difference between groups
No Baseline Esophageal Varices (n=81)	**7 (33)**	**3 (25)**	**2 (23)**	No difference between groups
New Esophageal Varices	**6**	**0**	**1**	**p = 0.02[2], PLB vs GR2** **p = 0.12[2], PLB vs GR8** **p = 0.01[2], PLB vs GR2 + GR8**

[2] Chi Square

[1] **Complications Include:**

1. Development of new esophageal varices
2. Progression to medium or large varices
3. Variceal hemorrhage
4. Clinically Significant Ascites
5. Spontaneous bacterial peritonitis
6. Overt Hepatic Encephalopathy
7. Increase in CPT Score ≥ 2
8. MELT score ≥ 15
9. Liver Transplant
10. Liver related death

Safety Results

	Total (n=162)	PLB (n=54)	GR2 (n=54)	GR8 (n=54)
All adverse events	1422	464	541	417
Grade 3-4 (patients (total events))	31 (69)	10 (19)	10 (22)	11 (28)
SAE[1] (patients (total events))	25 (39)	9 (13)	5 (10)	11 (16)
Rx stopped due to AE	5	0	0	5[2]
Death	1	0	1[3]	0
Grade 3/4 lab (patients (total events))	8 (15)	3 (3)	2 (2)	3 (10)

[1] Two SAEs were determined by the PI to be possibly related to study drug (transient ischemic attack and worsening of hyponatremia, both GR8); All others SAEs were felt to be unrelated to study drug

[2] *Possibly related to drug*: spasmodic cough (1); *Unrelated to study drug:* esophageal variceal bleeding (2), sepsis (1), pancreatitis (1)

[3] Pulmonary embolism following hernia repair surgery, judged to be unrelated to study drug

Major Conclusions from NASH-CX Clinical Trial Results

- **GR-MD-02 had a statistically significant and clinically meaningful effect in improving HVPG versus placebo in patients with NASH cirrhosis who did not have baseline esophageal varices**
  - Effect was seen regardless of the severity of the patient's baseline portal hypertension
  - Patients with esophageal varices may have masked benefits in the total population
- **Important drug effect in the total study population on liver biopsy, with a statistically significant improvement in hepatocyte ballooning (cell death)**
- **Statistically significant reduction in the development of varices in drug-treated patients compared to placebo**
- **While there was a drug effect in both dosage groups on liver biopsy and in the mild portal hypertension group, there was a consistently greater and statistically significant effect of the 2 mg/kg dose**
- **GR-MD-02 appears to be safe and well tolerated in this one year, phase 2b clinical trial**
- **We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with NASH cirrhosis without varices**

Discussion of Key Questions Raised by the Study Results

- **Why is there a differential effect of GR-MD-02 therapy in patients with and without esophageal varices?**
  - Liver biopsy showed an effect in all patients, so GR-MD-02 had a therapeutic benefit regardless of varices
  - The sensitivity and variability of the HVPG measurement to detect an improvement may be different in the presence of varices
- **How would the improvement in hepatocyte ballooning translate to an effect on portal hypertension?**
  - The death of liver cells triggers wide range of biochemical changes in the liver
  - This cascade of events from liver cell death might increase the resistance to blood flow through the liver
- **What is the reason for the more efficacious effect of the lower dose versus the higher dose of GR-MD-02?**
  - The sum of the data shows that there is clearly an effect of both doses of GR-MD-02
  - The 2 mg/kg dose had a more robust effect, which is most evident in the responder analysis which is the most rigorous assessment of efficacy because it requires a clinically significant *improvement* in HVPG from baseline
  - In an animal model of NASH, there was a similar effect of increasing drug doses on the NAFLD activity score [1]
  - These data suggest that higher doses of GR-MD-02 would not likely be more efficacious, and in future studies it may be logical to increase the duration of therapy to achieve a greater effect rather than increasing the dose

[1] *Traber PG and Zomer E. PLOS ONE 2013;8:e83481*

NASH-CX Trial: Next Steps

- **The trial results identify a significant patient population who may benefit from treatment with GR-MD-02**
  - Patients with well-compensated NASH cirrhosis without esophageal varices (Stage 1 cirrhosis)
  - Patients are readily identifiable since upper endoscopy for varices is recommended for all those with cirrhosis
- **The results suggest endpoints that may be employed in a phase 3 program**
  - Change in HVPG has been suggested by the FDA as a possible acceptable surrogate for outcomes in clinical trials
  - Change in HVPG could be used as an absolute or percentage change or as a responder analysis
  - The development of varices in patients without varices at baseline may be considered a clinical outcome measure
- **We currently have fast track designation for this program, and believe these clinical data will allow us to expedite development under the FDA's "breakthrough therapy" designation, for which we will apply**
- **These data will be submitted as a late-breaking abstract for presentation at the International Liver Congress in Paris, France in April 2018**
- **Discussions ongoing regarding phase 3 clinical trials for NASH cirrhosis without varices**

Galectin Therapeutics

Appendix

NASDAQ: GALT
www.galectintherapeutics.com

Appendix 1: Deep Gratitude to Patient Volunteers and Clinical Study Sites

Indiana University School of Medicine-Dr. Chalasani
The Texas Liver Institute-Dr. Lawitz
Duke University Medical Center-Dr. Abdelmalek
Feinberg School of Medicine - Northwestern University-Dr. Rinella
Pinnacle Clinical Research, PLLC-Dr. Harrison
Digestive and Liver Disease Specialists-Dr. Ryan
Cedars Sinai Medical Center-Dr. Noureddin
Digestive Health Specialists, PA-Dr. Jue
Medical University of South Carolina-Dr. Rocky
Thomas Jefferson University-Dr. Halegoua-De Marzio
Texas Clinical Research Institute LLC-Dr. Ghalib
Virginia Commonwealth University-Dr. Sanyal
University of Mississippi Medical Center-Dr. Borg
Bon Secours Richmond Health System-Dr. Shiffman
University of Colorado Denver-Dr. Wieland
Columbia University Medical Center-Dr. Wattacheril
University of Michigan-Dr. Conjeevaram
Mcguire Veterans Affairs Medical Center-Dr. Fuchs
Baylor College of Medicine-Dr. Vierling
Piedmont Hospital-Dr. Rubin
Mary Immaculate Hospital-Dr. Shiffman
Saint Louis University-Dr. Tetri
Mercy Medical Center-Dr. Thuluvath
Swedish Medical Center-Dr. Kowdley
UH Cleveland Medical Center-Dr. Gholam
International Medical Investigations Center-Dr. Rodriguez
Intermountain Medical Center-Dr. Charlton
Tulane University Health Sciences Center-Dr. Balart
Vanderbilt University Medical Center-Dr. Scanga
Walter Reed National Military Medical Center-Dr. Torres
Tampa General Medical Group-Dr. Kemmer
University of California San Diego Medical Center-Dr. Loomba
Beth Israel Deaconess Medical Center-Dr. Lai
University Gastroenterology-Dr. Sepe
Minnesota Gastroenterology PA-Dr. Zogg
Brooke Army Medical Center-Dr. Paredes

HVPG

Yale University School of Medicine-Dr. Garcia-Tsao

Liver Biosy

Inova Fairfax Hospital-Dr. Goodman

Appendix 2: Study Demographics[1]

	Total (FAS[2]) (162)	PLB[3] (n=54)	GR2[3] (n=54)	GR8[3] (n=54)
Age, years; Median (IQR)	59 (52, 65)	59 (53, 64)	60 (53, 65)	58 (51, 63)
Female, n (%)	113 (70)	36 (67)	34 (63)	43 (79)
White, n (%)	132 (81)	46 (85)	46 (85)	40 (74)
Hispanic/Latino, n (%)	28 (17)	8 (15)	7 (13)	13 (24)
Asian, n	1	0	1	0
Native Hawaiian, n	1	0	0	1
BMI, kg/m^2; Median (IQR)	34 (31, 39)	34 (30, 39)	36 (31, 41)	35 (31, 38)
Diabetes, n (%)	105 (65)	35 (65)	33 (61)	37 (69)

1 All subjects were enrolled across 36 sites in the United States
2 FAS = full analysis set, all subjects randomized
3 PLB = Placebo; GR2 = GR-MD-02 (2 mg/kg); GR8 = GR-MD-02 (8 mg/kg)

Appendix 3: HVPG at Baseline are Comparable Between Treatment Groups[1]

	Mean ± SD (n)	Total	PLB	GR2	GR8
Hepatic Venous Pressure Gradient	HVPG (mm Hg)	**12.2 ± 4.1 (162)**	**11.6 ± 3.9 (54)**	**12.3 ± 4.3 (54)**	**12.7 ± 4.2 (54)**
	CSPH[2] (mm Hg)	**14.3 ± 3.4 (109)**	**13.8 ± 3.1 (34)**	**14.2 ± 3.9 (37)**	**14.8 ± 3.1 (38)**
	MPH[3] (mm Hg)	**7.9 ± 1.2 (53)**	**7.8 ± 1.4 (20)**	**8.0 ± 3.3 (17)**	**7.6 ± 2.2 (16)**
	Neg Varices (mm Hg)	**10.6 ± 3.5 (81)**	**10.8 ± 3.8 (33)**	**10.4 ± 2.9 (25)**	**10.7 ± 3.8 (23)**
	Pos Varices (mm Hg)	**13.8 ± 4.2 (80)**	**12.7 ± 4.0 (21)**	**14.1 ± 4.6 (28)**	**14.2 ± 3.9 (31)**

[1] There were no statistical differences between the three treatment groups for any of the measures
[2] CSPH = clinically significant portal hypertension (≥ 10 mm Hg)
[3] MPH = mild portal hypertension ((≥ 6 and < 10 mm Hg)